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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,312	06/05/2001	Masumi Oshima	01458.00007	5718

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EXAMINER

BEHREND, HARVEY E

ART UNIT	PAPER NUMBER
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3641

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,312

Applicant(s)

OSHIMA ET AL.

Examiner

Harvey E. Behrend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is to a method of analyzing the nuclides in a sample including measuring the content of each nuclide by activating the sample with neutrons or gammas and using a multiple gamma-ray detector to detect a pair of gammas emitted from each of the nuclides in the radioactivated sample.

The specification on page 8 last line through page 9 line 15 shows how the invention is supposed to work when only one nuclide, Eu-152, is present and, this one nuclide simultaneously emits two gammas.

However, as indicated in the specification, any sample will have present many elements (with their various isotopes).

Clearly, in any given sample, there will be present, isotopes or nuclides that will be emitting gammas of many different energies and, that at least some of these gammas from different nuclides will be at the same energy or, close to the same energy, thus causing confusion as to which gamma came from which nuclide. Note for

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example in this respect that Ruddy et al show that gamma rays will be attenuated in energy as they pass through the sample to the detector. Pritchett (e.g. see cols. 2, 6) and Gaudin et al (e.g. see Table 1 and col. 2) show that gamma rays of substantially the same energy (interfering energies) can be produced by different nuclides or isotopes.

Additionally, pile-ups in the detectors can lead to errors as to the actual energy gamma ray(s) being detected. The disclosure is insufficient as to how and in what manner, such is accounted for.

There is no adequate description nor enabling disclosure of how and in what manner, applicant is able to determine which specific two of all of the gammas being emitted from all of the nuclides in the sample, are simultaneously emitted from the same, one nuclide. The specification on page 11 lines 20+ states that "signals from the two detectors are fed to a fast simultaneous counter which chooses only simultaneous counting events", however, such is insufficient and non-enabling as to how and in what manner, said "choosing" is actually accomplished and also, as to how and in what manner it is determined that the simultaneously counted events come from the same, one nuclide, rather than from the counting of gammas that were simultaneously emitted from different nuclides. The failure to disclose such places an undue burden on the artisan.

Note that such is necessary for applicants invention to actually be able to operate in the manner disclosed and claimed.

It appears from the references in the specification to tests or experiments done (pages 12+) and from the references in the specification to the various analyses

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(qualitative and quantitative), calibrations, correlations, etc., being done (see for example, page 8 lines 6+, page 10 lines 15+, page 11, page 13, page 15, etc.), that applicant is relying on the use of some unspecified algorithm(s), formula(s), computer program(s), etc., to perform the various analyses, calculations, determinations, etc., and, the specification is insufficient and non-enabling in failing to disclose such.

If applicant is of the opinion that there is a description in the prior art (in the form of literature, etc., having a date prior to the filing date of this application) of such suitable algorithm(s), formula(s), computer program(s), etc., copies of said literature, etc., must be submitted for appropriate review by the Office. See In re Ghiron et al, 169 USPQ 723, 727.

If “such suitable algorithm(s), formula(s), computer program(s), etc., “involve the use of constants, etc., to enable it to be applicable to different types of systems, there must also be a showing that it was known in the prior art as to how and in what manner, said constants, etc., could have been determined for applicants system.

The specification of page 13 lines 22+ and page 14 lines 2+, states that specified 49 and 23 elements respectively were determined. However, each of the listed elements themselves include plural isotopes. There is no adequate description nor enabling disclosure of how and in what manner, it was actually determined that each of said elements (and of which particular isotopes thereof) were actually present.

The specification and claims indicate that bombarding the sample with neutrons or gamma rays will cause each of the nuclides in the sample to emit a pair of gamma rays, but, they fail to recite the requisite energy level(s) of these bombarding neutrons or

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gamma rays and, the disclosure is hence insufficient and non-enabling. It is noted in this respect that the interaction cross-section of a nuclide with either a neutron or gamma ray is generally energy dependent. For example, some nuclides may react primarily with thermal neutrons while others may react primarily with fast neutrons. Further, a nuclide can produce a gamma ray by a neutron absorption reaction or by a neutron scattering reaction, dependent on the neutron energy. It would present an undue burden on the artisan to attempt to determine the requisite energy level(s) of bombarding neutrons or of bombarding gamma rays (as well as available sources with said requisite energy levels), to cause emission of a pair of gamma rays from each nuclide in the sample.

3. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventors has not been disclosed.

The specification on pages 12+ states that tests or experiments were done wherein up to 49 elements were determined and/or quantitated simultaneously using applicants inventive detection method, thus indicating that applicant was aware of and knew, the actual algorithm(s), formula(s), computer program(s), etc., (along with any appropriate constants), but, failed to disclose such as required by statute.

As indicate in MPEP 2165 and Union Carbide Corp. v. Borg-Warner, 193 USPQ 1:

"Failure to disclose the best mode need not rise to the level of active concealment or grossly inequitable conduct in order to support a rejection or invalidate a patent. Where an inventor knows of a specific material that will make possible the successful reproduction of the effects claimed by the patent, but does not disclose it, speaking instead in terms of broad categories, the best mode requirement has not been satisfied" See also, Spectra-Physics v. Coherent, 3 USPQ 2d 1737.

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4. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague, indefinite and incomplete.

Terms or phrases like "such as", etc., render the claims vague and indefinite as to exactly what is being claimed. The metes and bounds of the claims are hence undefined.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The use of a specified algorithm(s), formula(s), computer program(s), etc., necessary to actually be able to simultaneously measure all of the gammas emitted from a radioactivated sample and to determine which two gammas came from which specific nuclide (for each of the nuclides present in the sample) (note that it is impossible to operatively perform applicants detection method without such).

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any of Cole et al, Schultz et al or Horrocks et al.

The references each show the actual claimed method steps including the use of plural gamma ray detectors measuring a pair of gamma rays emitted from a nuclide, e.g. see Cole et al in col. 2 lines 17-38; Schultz et al in col. 2 lines 40+, col. 7 lines 17+, col. 8 lines 38-50; Horrocks et al in the abstract, col. 7 lines 38+.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gozani et al.

The reference shows the actual claimed method steps including the use of plural gamma ray detectors measuring a pair of gamma rays emitted from a nuclide (e.g. see

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col. 11 lines 22+ which refers to a plurality of gammas from nitrogen and a plurality of gammas from oxygen), using computer based analysis to construct a three-dimensional matrix (which inherently includes a two-dimensional matrix), and comparing the measured density and distribution for each nuclide to a standard or known database of information on these nuclides, thus performing qualitative and quantitative analyses of the nuclides (e.g. see col. 2, col. 7 line 22 to col. 8 line 11, col. 8 lines 21-52, col. 10, col. 13, col. 16, col. 17.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Cole et al, Schultz et al or Horrocks et al, in view of either Vourvopoulos et al or Gozani et al.

Gozani et al has been discussed above.

Vourvopoulos et al show it is old and advantageous in the art to compare or fit the measured spectrum to that of a known standard or library (e.g. see col. 7 lines 2-67).

While it is considered apparent and even inherent that in the practice of any of the primary references, one would inherently be comparing the measured spectrum to a known standard or library of nuclides, such would in any event, have been prima facie obvious in view of the above referenced teachings of either secondary reference.

10. The other references cited further illustrate pertinent art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harvey Behrend whose telephone number is (703) 305-1831. The examiner can normally be reached on Tuesday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Carone, can be reached on (703) 306-4198. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4195.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-1113.

A handwritten signature in black ink, appearing to read 'H. Behrend', with a stylized flourish at the end.

HARVEY E. BEHREND
PRIMARY EXAMINER

Behrend/vs
February 8, 2005